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Mark A. Hoffman

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EXAMINER

SIMS, JASON M

ART UNIT

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1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/981,248	<b>Applicant(s)</b> HOFFMAN ET AL.	
	<b>Examiner</b> JASON SIMS	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 85-89, 91-94 and 96-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85-89, 91-94, and 96-102 is/are rejected.
- 7) ☒ Claim(s) 85 and 103 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/1/2010 and 8/20/2010</u> .                                 | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicant's election without traverse of species two of claim 101 in the reply filed on 20/2/2011 is acknowledged.

Applicant's cancellation of claim 95 in the response filed 2/2/2011 is acknowledged and entered.

Applicant's arguments, filed 10/12/2010, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 20/2/2011, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 85-89, 91-94, and 96-103 are the current claims hereby under examination.

### ***Claim Objections***

The objection to claim 25 is being withdrawn as applicant has cancelled claim 25.

***The following is a newly applied objection, which has been necessitated by amendment:***

Claim 85 is objected to because of the following informalities: Claim 85 comprises the amended claim wording to read at lines 6-7 "whether to authorize performing a genetic test ***on a when*** a genetic test result is unavailable for the person." It appears that either the words "on a" should be deleted or the word "patient" should be inserted. Appropriate correction is required.

Claim 103 is objected to because of the following informalities: Claim 103 depends from a cancelled claim, (claim 35) and thus is improperly dependent. As such it has not been treated on the merits in the instant Office Action. Appropriate correction is required.

***The following rejection is being newly applied, which was necessitated by amendment:***

***Claim Rejections - 35 USC § 112-First Paragraph***

Claims 85-89 and 96-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 85 (and all claims dependent therefrom) has been amended to recite a decision tree to reflect when demographic information about the person is inaccessible, utilizing genetic variability of a general population for calculating a second likelihood that the person displays genetic variability linked with genes associated with the genetic test, wherein the decision tree has been deemed as new matter. Applicant pointed to paragraphs [0040] – [0042] and [0049] – [0050] for support for said decision tree. However, said referenced paragraphs support for performing the calculation if a genetic test result is not available or if demographic information is available adjust the calculations. In addition, newly admitted claim 94, step (b) (and all claims dependent

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therefrom) comprises the same decision tree with regards to whether demographic information is not available, which also constitutes new matter. Appropriate correction is required.

***The following rejection is being newly applied, which was necessitated by amendment:***

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 101-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 101 and all claims dependent therefrom recites the limitation "wherein the second data set" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is unclear as to what second data set the claim refers. Because it is unclear as to what second data set the claim refers, the claim is vague and indefinite as to its metes and bounds. Clarification via clearer claim wording is required.

***Claim Rejections - 35 USC § 103-Maintained/Modified***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 85-89, 91-94, and 96-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) and REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000) and further in view of Fey et al. (US Pub. 2002/0038227, filed 2/26/01), further in view of Hogan (US A/N 2002/0110823), in view of Bowie (US P/N 5,750,345) and further in view of Levine et al. (US P/N 2003/0011646).

Claims 85, 91, and 94 are directed to a computer-implemented method and/or computer program implementing instructions for processing hereditary data, and to a computer system and medium comprising instructions or components for performing the method, wherein the method comprises receiving a genetic test result value for a person, querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents, and outputting an "interpretation" of the genetic test result value and the list of risk-associated agents. Claim 55 comprises amended further limitations directed towards automatically obtaining genetic test result values and further limitations towards a process for obtaining a genetic test result value.

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Claim 85 comprises amended further limitations directed to displaying notification windows in the GUI, comprising likelihoods of a patient having the genetic variabilities. Claims 26, 56, 86 and 91 further limit the method to comprise determining if a patient has been exposed to a risk-associated agent. Claims 57 and 87 limit the method to further comprise accessing an electronic medical record. Claims 59-60 and 89-90 limit the method to comprise initiating a clinical action if a patient has been exposed to a risk-associated agent, specifically to inform a clinician to no longer administer the agent. Claim 93 limits the method to comprise determining whether to authorize in accordance with cost of the genetic test, a likelihood of a genetic variation based on demographic information of the patient and either automatically or through the physician ordering the genetic test.

ICHIKAWA teaches a method for processing hereditary (genetic) data related to response to azathioprine or mercaptopurine (clinical agents) wherein genetic tests results for individual patients are received, the presence of a polymorphism is determined, wherein particular mutations or polymorphisms are associated with atypical clinical events (side effects) of administration of various drugs, and a decision made to change a drug dosage (p. 523). Since drug dosages are based on the genetic testing results in the method of ICHIKAWA, the method necessarily includes a step of outputting the test results and the list of drugs. ICHIKAWA also teaches that one decision based on the results may be discontinuation of drug use (p. 523, left column). ICHIKAWA does not specifically teach querying a computerized table listing polymorphism values and atypical events associated with the polymorphism values,

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electronic medical records, a computer-implemented method, a computer system or a computer-readable medium.

EVANS teaches association of a variety of drugs with polymorphisms, which are also known to be associated with “idiosyncratic” drug reactions or altered drug sensitivity (p. 489, Table 1), thus teaching a list of “risk-associated agents”. EVANS teaches that his Table 1 is a computerized table of atypical clinical events associated with polymorphism values (see the legend for Table 1 which states “A comprehensive listing is available at [www.sciencemag.org/feature/data/104449.shl](http://www.sciencemag.org/feature/data/104449.shl)”). It is noted that Table 1 of EVANS includes the drugs and at least one of the polymorphic sites taught by ICHIKAWA. It is further noted that the table of EVANS contains many of the genes, polymorphic sites, and atypical events disclosed by the instant specification in Table 2 on page 16. EVANS also teaches automated systems to associate an individual’s genotype with polymorphic genes in order to optimize drug administration and disease treatment (p. 490, right column). EVANS does not specifically teach accessing an electronic medical record.

REINHOFF teaches a computer-implemented method, and a system and computer-readable medium comprising instructions for performing the method, wherein information with regard to a patient’s polymorphic profile is linked to a degree of response of the patient to a treatment, specifically to side effects; i.e. an “atypical” clinical response (paragraphs 33, 38, 57 and 59). Specifically, REINHOFF teaches populating a computerized database with genotypic and phenotypic data (para 38) and teaches that polymorphic profiles of individuals may be associated with response to



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drugs in a computerized method (para 57). He further teaches analysis of such data in a computerized database (para 58), thus teaching a step of “querying” a computerized listing comprising polymorphic data and atypical clinical events associated with the polymorphic data. REINHOFF also teaches that a variety of electronic medical and/or clinical records may be accessed in his method (paragraph 27).

It would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of ICHIKAWA, as taught by REINHOFF, and to have accessed/queried a computerized list of treatment/drug options, as taught by EVANS, in the automated method of ICHIKAWA and REINHOFF, where the motivation would have been to facilitate use of the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by REINHOFF (paragraph 59) and/or to determine an appropriate dosage of the agent, as taught by REINHOFF (paragraph 57) and ICHIKAWA (p. 523, left column, last paragraph).

REINHOFF suggests, but does not explicitly recite a graphical user interface having specific functionality.

REINHOFF suggests this because REINHOFF teaches, at paragraph [0040] computers running customized software supporting the service provided by the taught invention, wherein it is common for software to have built in GUIs for easier functionality for a user. Furthermore, REINHOFF teaches at paragraph [0010] that the computer program product allows identification of a susceptibility locus in individuals using genetic screening methods to assess an individual's risk of certain disease, i.e. it is commonly

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understood wherein a doctor would perform the risk assessment thereby implying that the networked system comprising the program product is intended not just for patients, but also doctors or hospitals.

Fey et al. teach at paragraphs [0022] [0048] and [0055] an application of health data management which involves a graphical user interface written for web browser applications wherein the user has a unique identification and may enter information through the GUI. Fey et al. at paragraph [0012] teach keeping secure health records, which are accessible by authorized health persons. Fey et al. further teach that custom reports are generated at the time tests are performed that explains the results. Fey et al. teach at paragraph [0022] wherein results are prepared for the individual and physician. Fey et al. teach at paragraph [0047] wherein the health data may be used by doctors. In addition, Fey et al. at paragraphs [0053] – [0059] and [0063] – [0075] teach a system comprising a means, i.e. a displaying component and computer storage media configured for displaying a graphical user interface as in claims 55 and 85. With further regards to claim 85, Fey et al. teach at paragraph [0031] storing the genetic test results.

Fey et al. does not explicitly teach a GUI that is configured to solicit input from a clinician to ascertain whether to authorize performing a genetic test on a patient. In fact, Fey et al. teach, i.e. paragraph [0057] that the invention is directed to enabling a client/consumer to order genetic testing without doctor's approval. Furthermore, Fey et al. teach that a client can use the taught invention to determine genetic risk towards disease or conditions or discover genetic predispositions.

Although it appears that the invention of Fey et al. does not actually teach a physician based system, it is the functionality of said system, which is taught that is the focus. The invention taught by Fey et al. has the functionality of using a graphical user interface to solicit input, albeit a client, to ascertain whether to perform a genetic test, displays identification of the genetic test to be performed, receives approval or authorization from the client to carry out the genetic test, ensures identification of the person, and is configured to receive result value of the genetic test for the person.

Hogan at the abstract discusses a method for tailoring a subject's surgical treatment to reflect genetic information. Hogan at paragraph [0005] discusses that the choice of anesthetic regimen, agent, and dose depends on the type of surgery or procedure. Hogan at paragraphs [0011] – [0013] discusses genomic screening of a subject prior or during a surgical procedure to obtain a genomic profile. Hogan at paragraphs [0019] – [0022] discusses obtaining a genomic profile for a subject which screens the subject for one or more polymorphism values associated with one or more clinical events associated with one or more clinical agents. Hogan at paragraphs [0018] and [0019] discusses screening a patient to determine a risk for surgical complications associated with known genetic variations. Hogan teaches at paragraph [0187] and Fig. 1, automated processes for obtaining a genetic test result value. Hogan teaches at paragraphs [0032] – [0038] and [0187] analyzing the cost-benefit of genomic profiling, which further reads on amended limitations of claim 55. Furthermore, Hogan at paragraph [0190] discusses that the risk assessment for the various treatment options are displayed to the clinician on a computer monitor, which reads on displaying to the

clinician a list of risk-associated agents, a warning of the effects of the polymorphism value, and alternate clinical agents that are not associated with the polymorphism value.

Additionally, Hogan at paragraph [0187] they teach a set of criteria to be met prior to administering a genetic test or genomic profile test, such as whether the subject is a candidate for genomic profiling, if a particular method is available for performing said test, if the method will provide useful information for a particular application and its practicality, and if there is clinical utility, i.e. provide a predication of a phenotype related to the genotype. Hogan at paragraphs [0005], [0008], and [0138] discusses assessing the dosages associated with the clinical agents and risk assessments. Hogan at paragraphs [0186] and [0188] – [0193] discusses that the clinical agent and genetic information may be stored and communicated via various computerized applications, including electronic medical records including computers. Hogan at paragraph [0031] – [0033] discusses a problem is “how to alter treatment course of action in response to results,” as in genomic screening results and the present invention unites “medicine with genetics” to solve the described problem and to individualize treatment options for each subject. Hogan at paragraphs [0190] – [0191] teaches outputting information about the atypical clinical event associated with the polymorphism values such that a “clinical action” may be initiated. Hogan at paragraph [0190] discusses that the risk assessment for the various treatment options are displayed to the clinician on a computer monitor. Furthermore, Hogan at paragraphs [0115], [0129], [0136] – [0147], and [0186] teaches comparing genetic test result values for multiple genes to polymorphoism values

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associated with adverse reactions, i.e. risks associated with atypical clinical events, and that agent information may include dosage and other PK/PD parameters.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the system for authorizing genetic tests and displaying results, etc. as taught by Fey et al. and Hogan for use by a physician as taught by REINHOFF, ICHIKAWA and EVANS. This is because REINHOFF teaches a program product for studying genetic data and using genetic screening methods to assess increased risk of certain diseases and conduct basic research on population genetics. It would have been obvious to the skilled artisan to improve the invention of REINHOFF by adding a secured health data management system, wherein a physician can ascertain whether to authorize performing a genetic test on a patient based on their assessed risk for a certain disease. REINHOFF teaches at paragraphs [0008] – [0009] using a web system to create polymorphic profiles for individuals. Therefore, creating a secured health data management system wherein the polymorphic profiles are stored and further genetic tests can be authorized as deemed necessary can be seen as an improvement wherein the results would be predictable. Moreover, a skilled artisan would find that the differences between the claimed invention and the prior art were encompassed in known variations or in a principal known in the prior art.

The combination of REINHOFF, Fey et al., ICHIKAWA, EVANS, and HOGAN do not explicitly teach the limitation of the specific decision tree wherein when demographic information is inaccessible perform the step of utilizing genetic variability of a general

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population for calculating a second likelihood that the person displays genetic variability linked with genes associated with the genetic test.

Bowie teach at col. 5, lines 4-19 wherein the method of calculating risk, i.e. likelihood, of a person displaying genetic variability using the genetic variability of a general population is a known and practice method.

It would have been obvious to one of ordinary skill in the art to have used the method taught by Bowie of calculating risk when particular information was unavailable for use in the method taught by the combination of REINHOFF, Fey et al., ICHIKAWA, EVANS, and HOGAN. This is because Hogan at paragraph [0037] teach that sometimes at the time of surgery genomic profiles are unavailable, but the information would still be helpful and effective to have. One of ordinary skill in the art would have recognized that applying the known method of method of calculating risk, i.e. likelihood, of a person displaying genetic variability using the genetic variability of a general population in the method of customizing treatments based on risk as taught by the combination of REINHOFF, Fey et al., ICHIKAWA, EVANS, and HOGAN would have yielded predictable results and resulted in an improved method. Furthermore, Hogan teaches decision trees based on available information with regards to determining the use of clinical agents based on hereditary information. Thus one of ordinary skill in the art would have immediately recognized that the method taught by Bowie would have been applicable in an analogous decision tree as encompassed by the instantly claimed method. This is because the differences between the claimed invention and the prior art were encompassed in known variation or in a principal known in the prior art.

The combination of REINHOF, Fey et al., ICHIKAWA, EVANS, HOGAN and Bowie do not explicitly teach the limitation of a button, that when selected, directs the clinician to addition information regarding the association of the clinical agent and a genetic mutation linked to the polymorphism value.

Levine et al. teach an invention that is directed to the clinical management of chronic illness comprising GUIs that interface between clinician and patient. Levine et al. teach the commonly used functionality of adding buttons to GUIs throughout the Figures and throughout the reference, i.e. see paragraph [0099]. Levine et al. teach at paragraph [0116] the GUI comprising a link or interface widget, i.e. button, to associated information that is contextually relevant information, which may be displayed. Thus Levine et al. discloses the known practices of those skilled in the art of providing diverse functionalities of GUIs in a clinical setting.

It would have been obvious to one of ordinary skill in the art to have designed a GUI that comprised a button for a practitioner in order to pull up relevant or associated clinical information as taught by Levine et al. for use in the method taught by the combination of REINHOF, ICHIKAWA, EVANS, and HOGAN and Bowie. This is because the combination of references teaches the manual procedure of looking up clinically relevant information such as information regarding an association of a clinical agent and a genetic mutation. The combination of references further teaches using computer systems and GUIs for use in clinical setting. Therefore, one of ordinary skill in the art could have applied the known method of adding buttons to GUIs as taught by Levine et al. in the same way to the already known manual procedure of seeking

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clinically relevant information and using GUIs and automated systems as also taught and the results would have been predictable to one of ordinary skill in the art.

Fey et al. does not explicitly teach automatically scheduling counseling for the person, automatically ordering follow-up tests, nor automatically providing a notification in an email address to a physician that informs the physician to no longer administer the agent, wherein the physician is identified by the person's electronic medical record.

However, Fey et al. teach at paragraph [0042] generating custom reports of the genetic tests. Fey et al. further teach at paragraph [0044] the data is analyzed in conjunction with known medical data, such as disease, risk factors, screening factors, etc. Fey et al. at paragraph [0045] teach that the personalized health record reviews health risks and thoroughly explains test results with follow-up recommendations and determine further health risks.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have automated particular follow-up recommendations such as ordering another genetic test based on a health record or sending an email message to discontinue the administration of a particular drug with known adverse effects on the client with a particular genetic predisposition in the method of Ichikawa, Reinhoff, Evans, Fey and Hogan and Bowie. This is because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level and monitor their potential health risks based on genetic screening. Therefore, an automated result to a physician indicating an adverse effect of a particular drug being taken would be seen as an obvious improvement to the health management



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system where the results would have been predictable to one of ordinary skill in the art. Furthermore, automation of known methods, such as further automating the automated follow-up recommendations would be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. does not explicitly teach ascertaining whether to automatically generate a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents as in claim 91.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have have ascertained a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents when generating the follow-up recommendations as taught by Fey et al.. This is because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level and monitor their potential health risks based on genetic screening. Therefore, an automated result ascertaining a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-

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risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents, when generating the follow-up recommendations as taught by Fey et al. would be seen as an obvious improvement to the health management system where the results would have been predictable to one of ordinary skill in the art. Furthermore, automation of known methods, such as further automating the automated follow-up recommendations would be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. teach at paragraphs [0019] and [0049] that the medical records are accessible and updating the healthcare system, wherein updating integrates heredity data with newfound knowledge as in claim 86.

With regards to claim 93, Hogan at paragraph [0187] teaches information generated by perioperative genomic profiling is automated. Hogan at paragraph [0187] they teach a set of criteria to be met prior to administering a genetic test or genomic profile test, such as whether the subject is a candidate for genomic profiling, if a particular method is available for performing said test, if the method will provide useful information for a particular application and its practicality, and if there is clinical utility, i.e. provide a predication of a phenotype related to the genotype. Hogan at the background and paragraphs [0030] – [0034] discuss the cost-effectiveness and importance of it when performing perioperative testing of patients, i.e. genomic profiling. Furthermore, at paragraphs [0119] – [0127] Hogan teaches that only markers that correlate with a subject's response or ones that can provide effective and helpful information are included in obtaining a genomic profile. Hogan at paragraph [0031] –

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[0033] discusses a problem is “how to alter treatment course of action in response to results,” as in genomic screening results and the present invention unites “medicine with genetics” to solve the described problem and to individualize treatment options for each subject. Thus, Ichikawa, Reinhoff, Evans, Fey, Hogan, and Bowie make the claimed invention obvious.

### ***Response to Arguments***

Applicant's arguments with respect to claims 85-89, 91-94, and 96-102 have been considered but are moot in view of the new ground(s) of rejection.

However with regards to applicant's arguments that the combination of references does not teach the step of calculating risk, i.e. likelihood, of a person displaying genetic variability using the genetic variability of a general population, they are not found persuasive as the reference Bowie teaches the known method as described above in the instant office action.

Furthermore, with regards to applicant's arguments that Classen does not teach particular limitations, they are not found persuasive as they are directed to a reference not cited in the previous Office Action.

Applicant argues at pages 8-12 that the limitations of claim 91 with regards to a dual response system, a low-risk or high-risk response are novel over the prior art of record. Applicant specifically alleges that the decision is based on two-criteria, i.e. whether a person has been exposed to an agent or whether a dosage of the agent exceeds a predetermined level.

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Applicant's arguments are not found persuasive as Hogan throughout the reference is directed to customizing treatments according to genomic profiles as acknowledged by applicant. Furthermore, Hogan at paragraph [0037] describes how in emergency situations, such as emergency surgeries, wherein genomic profiles are unavailable, obtaining the information is still effective and helpful. It is helpful as it will further generate a dual-response system with regards to the correlations described throughout in Hogan reference. If the genomic profile information is returned and the patient has been exposed to a clinical agent that may cause atypical responses or life-threatening responses, the level of potential response will dictate the response, i.e. patient will be put in intensive care monitoring, or other treatments may be administered. The different responses are a part of the decision trees taught by Hogan and make the instantly claimed invention, when combined with the other references, obvious.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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(November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)).  
The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /